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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/541,083	06/29/2005	Michael T. Carley	16497.1.1.1F	1182	
57360	7590	10/16/2007	EXAMINER		
WORKMAN NYDEGGER 1000 EAGLE GATE TOWER, 60 EAST SOUTH TEMPLE SALT LAKE CITY, UT 84111		VELASQUEZ, VANESSA T			
		ART UNIT		PAPER NUMBER	
		4116			
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/541,083	CARLEY ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Vanessa T. Velasquez	4116

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 29 June 2005.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-16 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-16 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 29 June 2005 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____.
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>06/29/2005</u>	5) <input type="checkbox"/> Notice of Informal Patent Application
	6) <input type="checkbox"/> Other: _____.

## **DETAILED ACTION**

### ***Status of Application***

Claims 1-16 are pending and are presented for examination.

### ***Priority***

Priority claim to U.S. Application No. 10/335,075 filed on December 31, 2002 is acknowledged.

### ***Information Disclosure Statement***

1. An information disclosure statement (IDS) was submitted on June 29, 2005. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner is considering the information disclosure statement.
2. Please note a typographical error regarding citation AB by Loshakove et al. The correct document number is U.S. Patent 6,726,704.

### ***Drawings***

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following figure mentioned in the description: FIG. 3D on p. 5 (Line 18).

4. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 50 in FIG. 6.

Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the examiner does not accept the changes, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1, 8, and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. The term "generally" in claims 1 and 8 is a relative term that renders the claim indefinite. The term "generally" is not defined by the claim, the specification does not

provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear the extent to which the body is annular or planar.

8. The term "substantially" in claims 1 and 8 is a relative term that renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear the percentage the alloy is austenitic (claims 1 and 8), the lateral dimension of the precursor compared to the clip (claim 8), and the proximity of the tines that point radially inward (claim 8).

9. Claim 8 recites the clause "said precursor having a lateral dimension which is substantially larger than that of the clip." It is unusual to describe annular bodies using lateral dimensions. Circles, for instance, are not characterized by the number of sides present. Clarification is required.

10. Claim 13 recites the limitation "after compression." There is insufficient antecedent basis for this limitation in the claim. Examiner will interpret claim 13 to be dependent on claim 8 rather than on claim 1.

#### ***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miura (U.S. Pat. 5,092,941) in view of Peterson et al. (U.S. Pat. 6,152,937).

Miura teaches a method of shaping a medical device by mechanically forming a shape-memory alloy and subjecting the alloy to temperatures sufficient to retain the formed shape.

Regarding claims 1 and 2, Miura teaches the steps of deforming a wire to a predetermined shape, heating the wire, and cooling the wire (Col. 3, Lines 28-36; Col. 2, Lines 42-50). The wire can be a superelastic alloy such as nickel-titanium (Miura, Col. 2, Lines 51-53). Although Miura does not explicitly refer to the martensitic-austenitic phase transformation, it is inherent in the processing steps described. The nickel-titanium alloy is heated to about 500°C (Miura, Col. 2, Line 53), which is a temperature sufficient to form austenite (see supporting reference by Cruz et al., U.S. Pat. 5,858,082, Col. 2 Lines 50-67, Col. 3 Lines 1-10).

Miura fails to teach an annular, planar clip comprising one or more tines, and further fails to teach an inverting step in which the tines initially extend radially outward and subsequently inward after inversion.

Peterson teaches a medical graft connector and a method of producing the connector. The connector is annular, planar, and possesses a plurality of tines that extend radially outward. Although Peterson does not express an inverting step, it would have been obvious to one of ordinary skill in the art to implement such a bending motion in order to obtain a desired final shape (Peterson, Col. 6, Lines 35-37). Radially inward tines would be a natural result of inverting an object that initially had radially outward tines.

Regarding claims 3-7, Peterson teaches a connector that comprises a plurality of loops (FIG. 1, Part 20). The fingers are next to each other (FIG. 1, Part 16 in relation to 18) and also stacked one on the other (FIG. 1, Part 18 in relation to 20). The fingers that oppose one another are of unequal lengths (FIG. 1, Part 16 in relation to radially opposite part 18). A sheet of material is cut or machined to form the connector (Col. 5, Lines 48-52).

One of ordinary skill at the time of the invention could modify the process of Miura to include the shaping steps by Peterson because the two processes together yield a simple, biomedical device capable of connecting tubular structures. The heat treatment steps by Miura are essential for obtaining the mechanical properties associated with shape-memory alloys. Shape-memory alloys are well known for use in surgical equipment and medical devices (e.g., Peterson, Col. 1, Lines 58-64).

Furthermore, the structure taught by Peterson aids in connecting tissue (FIG. 14) without the use of sutures.

14. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Miura (U.S. Pat. 5,092,941) in view of Peterson et al. (U.S. Pat. 6,152,937).

Claim 14 claims the product as a result of the process recited in claim 1; therefore, it is rejected under the same premises applied to claim 1.

15. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Miura (U.S. Pat. 5,092,941) in view of Peterson et al. (U.S. Pat. 6,152,937).

Claim 15 claims the product as a result of the process recited in claim 6; therefore, it is rejected under the same premises applied to claim 6.

16. Claims 8-10 and 12-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miura (U.S. Pat. 5,092,941) in view of Peterson et al. (U.S. Pat. 6,152,937).

Regarding claims 8-10 and 12-13, Miura in view of Peterson teaches all the limitations stated above (refer to analyses of claims 1-5) except the compressing step.

Peterson describes the connector as being "radially deformable between a first size and a second size" (Col. 2, Lines 3-4). The radius of the connector can change with the application of a force in the radial direction. One of ordinary skill in the art could modify Miura to include a compressing step because it would be necessary to change

Art Unit: 4116

the radius of the connector in order to mount it on a connector apparatus (Peterson, Col. 8, Lines 45-57; see FIG. 8). Proper mounting on the apparatus is essential for loading the connector in the body and connecting conduit to vessel correctly.

17. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Miura (U.S. Pat. 5,092,941) in view of Peterson et al. (U.S. Pat. 6,152,937) as applied to claims 8 and 9 above, and further in view of Kleshinski et al. (U.S. Pat. 5,540,712).

Miura in view of Peterson teaches all the limitations as stated above (refer to analyses of claims 8 and 9) except the orientation of the grain with respect to the tine.

Kleshinski teaches a medical stent made of nickel-titanium alloy. In Kleshinski's invention, the longitudinal axis of the stent is oriented orthogonal to the grain of the Nitinol (Col. 9, Lines 31-37). One of ordinary skill in the art at the time of the invention could modify Miura in view of Peterson by orienting the austenitic grains 90 degrees with respect to a pair of fingers of the connector because doing so would improve the mechanical properties of the device (Kleshinski, Col. 9, Lines 13-27).

18. Claim 16 is rejected under ~~35 U.S.C. 103(a)~~ as being unpatentable over Miura (U.S. Pat. 5,092,941) in view of Peterson et al. (U.S. Pat. 6,152,937).

Claim 16 claims the product as a result of the process recited in claim 8; therefore, it is rejected under the same premises applied to claim 8.

***Citation of Pertinent Art***

19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.
20. U.S. Pat. 5,335,680 Moore teaches a hair clip with radially opposing "tines" of different lengths.
21. Stretch Comb by Scunci Stretch combs are flexible headbands that have multiple teeth that face radially inward to comb the hair back and away from the face. The structure of the hair clip is similar to FIG. 1A. The bending motions one must apply in order to wear the clip involve both inversion and compression.
22. U.S. Pat. 6,623,510 Carley et al. teach a surgical clip (see various figures) nearly identical to the clips in the instant application.
23. U.S. Pat. 6,719,777 Ginn et al. teach a surgical clip (see various figures) substantially similar to the clips in the instant application.
24. WO 00/56223 Loshakove et al. teach a vascular closure device (see figure A on the cover sheet) similar to the clips in the instant application.

***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vanessa T. Velasquez whose telephone number is 571-270-3587. The examiner can normally be reached on Monday-Friday 8:00 AM-5:30 PM EDT.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on 571-272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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